

### Remarks

Applicant believes that the comments that follow will convince the Examiner that the rejections provided in the March 29, 2007 Office Action have been overcome and should be withdrawn. Claims 30-33 remain for consideration.

#### I. THE EXAMINER'S REJECTIONS

The Examiner rejected claims 30-33 under 35 U.S.C. § 102 as being anticipated by Dasseux *et al.* U.S. Patent No. 6,680,203 (hereinafter "Dasseux"). Regarding claim 30, the Examiner stated that Dasseux discloses "a method of analyzing a drug-dosed sample that includes ionizing a drug-dosed sample with metabolic products"; "introducing said ions to the analysis region of a mass spectrometer"; "continuously monitoring the ions and detecting changes to the sample"; "determining the molecular weight of each species present in a sample to determine the empirical formula" and "identifying each species by comparing the empirical formula to a database of formulas."

Regarding claim 31, the Examiner stated that Dasseux teaches "updating databases with the changes that are detected."

Regarding claim 32, the Examiner stated that Dasseux teaches "where the mass spectrometer is a FTMS."

Regarding claim 33, the Examiner stated that Dasseux teaches "using electrospray ionization[ ] as well as chemical ionization."

**II. THE EXAMINER'S REJECTIONS AND OBJECTIONS SHOULD BE RECONSIDERED AND WITHDRAWN**

The Examiner rejected claims 30-33 under 35 U.S.C. § 102(e) (1) as being anticipated by Dasseux. Applicant respectfully disagrees and submits that Dasseux does not disclose all of the elements of the present application.

The Examiner stated that Dasseux discloses "continuously monitoring the ions and detecting changes to the sample" at Dasseux, page 15, paragraph 0153. This is not the case. At page 15, paragraph 0153, Dasseux discloses:

A brief explanation of how the XMASS software organizes spectra is in order. The organization is based entirely on directory hierarchies. A directory is selected where data should be stored as samples are processed. As the samples are processed, they are numbered from one to the total number of samples, and each sample result (spectrum and supporting information) is placed into a subdirectory named for the sample number (XMASS refers to this as an experiment number). Within these experiment number directories, there is a subdirectory called pdata, which has subdirectories numbered, starting with 1, for each time the sample is analyzed (each has its own spectrum). It is within this directory that the ASCII peak files are written. Because the XMASS software has no convenient way of tracking experimental conditions, careful notes must be taken during the processing of samples to relate the generated experiment numbers to these conditions.

In short, Dasseux merely discloses "how the XMASS software organizes spectra." The XMASS software takes the spectra from the samples and "numbered from one to the total number of samples." In addition, "careful notes must be taken during the processing of samples" so that the experimental conditions can be noted. Therefore, the XMASS software does not continuously monitor the ions and detect changes to the sample.

The Examiner also stated Dasseux discloses "determining the molecular weight of each species present in a sample to determine the empirical formula and identifying each species by comparing the empirical formula to a database of formulas" at Dasseux, page

17, paragraph 0169. This too is not the case. At page 17, paragraph 0169, Dasseux discloses:

Comparison of mass spectra of extracts from test samples (e.g., from potentially diseased cells or cells treated with a test compound) compared to controls or reference samples (e.g., from normal or untreated cells) allows the identification of peaks that are increased or decreased (e.g., with the dose of the drugs or the severity of the disease) as well as peaks that do not vary. Knowing the exact mass of the peak, it could be easy to identify the molecule (either directly in the case of a small molecule or by elucidating the chemical formula of one or more fragments in the case of a large molecule). The first step is to determine the peaks for small molecules. **There at least two ways of determining the general formula. First, common elements, including but not limited to C, N, H and O, are used in a linear combination to reconstitute the molecule.** As will be appreciated by those in the art, in some cases the molecular mass will take into account an extra proton or an extra atom (for example a sodium atom in the case where the compound is sodiated). Multiple possibilities are evaluated using associated statistical probabilities. **A second approach is to search the appropriate databases based on known molecular mass, taking into account isotope abundance.** Of the possible candidates, only biological entries will be considered. For large molecules, a fragmentation step is used to enable the identification of the molecule. In addition, the consideration of multiple charged peaks will be used. (emphasis added).

Dasseux discloses the “two ways of determining the general formula.” The first way is by using common elements in a linear combination to “reconstitute the molecule”. The second way is to “search the appropriate databases based on known molecular mass.” Therefore, Dasseux determines the general formula of a sample by either using “common elements...in a linear combination to reconstitute the molecule” or by “search[ing] the appropriate databases based on known molecular mass.”

In contrast, claim 30 of the present application requires the steps of “continuously monitoring said ions”; “detecting changes to said sample”; “determining a molecular weight of each species present in said sample to determine an empirical formula of said sample”; and “identifying each species by comparing said empirical formula to a

database of formulas for known molecules.” As discussed above, Dasseux’s XMASS software does not continuously monitor the ions and detect changes to the sample. Furthermore, Dasseux determines the general formula of a sample by either using “common elements...in a linear combination to reconstitute the molecule” or by “search[ing] the appropriate databases based on known molecular mass.”

Therefore, Applicant respectfully submits that claim 30 is not anticipated by Dasseux and is in condition for allowance. The Examiner is respectfully requested to withdraw the rejection.

With regard to claim 31, the Examiner stated that Dasseux teach updating databases with the changes that are detected at Dasseux. (page 18, paragraph 0183 and page 19, paragraphs 0186-0187). Applicant respectfully disagrees. At page 18, paragraph 0183, Dasseux discloses:

Thus, the present invention finds utility in a wide variety of applications. In a preferred embodiment, the methods outlined herein are used to analyze samples and build and access databases. In a preferred embodiment, the methods allow the generation of a wide variety of databases, particularly for but not limited to small molecules, since the FTMS allows such high precision.

At page 19, paragraphs 0186-0187, Dasseux discloses:

Thus, by running large numbers of samples from a variety of different sources and under different conditions, databases of data are generated. These can be used in a variety of ways. In a preferred embodiment, the databases are used in further experiments to identify peaks. Alternatively, they can be used to compare samples or the effects of drugs or candidate agents on samples, to identify signaling pathways and therapeutically relevant components.

In addition, when the databases are generated, they may be visualized using any number of graphical representation software, including visualization software such as SPOTFIRE.RTM., 3D contour mapping, topology mapping, triangulation techniques, etc.

Therefore, Dasseux discloses “the generation of a wide variety of databases.” The generated databases are “used in further experiments to identify peaks.” However, nowhere does Dasseux disclose “updating the databases with the changes that are detected” as suggested by the Examiner.

In contrast, claim 31 of the present application requires “said database [to be] updated with changes that are detected.” Therefore, the Applicant respectfully submits that claim 31 is not anticipated by Dasseux and is in condition for allowance. The Examiner is respectfully requested to withdraw the rejection.

As discussed above, Dasseux fails to disclose all the elements of independent claim 30. Dependent claims 31-33 are dependent on and contain all of the limitations of allowable independent claim 30 and are also not anticipated by Dasseux and are therefore in condition for allowance. The Examiner is respectfully requested to withdraw the rejection of claims 31-33.

**III. Conclusion**

Applicant submits that the all pending claims represent a patentable contribution to the art and are in condition for allowance. Early and favorable action is accordingly solicited.

Respectfully submitted,

Dated: October 1, 2007

A handwritten signature in black ink, appearing to read "D. Hill", written over a horizontal line.

David M. Hill  
Reg. No. 46,170  
WARD & OLIVO  
380 Madison Avenue  
New York, New York 10017  
(212) 697-6262